

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Tai-Shun Lin and William H. Prusoff
Serial No. : 06/942,666
Filed : December 17, 1986
For : USE OF 3'-DEOXYTHYMIDIN-2'-ENE (3' DEOXY-
2',3'-DIDEHYDROTHYMIDINE) IN TREATING
PATIENTS INFECTED WITH RETROVIRUSES
Art Unit : 123
Examiner : J. Tou

Hon. Commissioner of Patents
& Trademarks
Washington, D.C. 20231

Sir:

DECLARATION UNDER RULE 132 OF DR. J.P. SOMMADOSSI

I, Dr. J. P. Sommadossi do depose, declare and state that

1. Appended hereto and made a part hereof is my curriculum vitae which gives details of my background and experience. Based on such background and experience, I believe I am an expert in the field of the above-identified patent application.

2. I am not an applicant of the above-identified patent application.

3. Appended hereto is a copy of an Abstract from the International Society for Antiviral Research, Second International Conference on Antiviral Research, Williamsburg, Virginia, April 10-14, 1988. The Abstract is entitled "2',3'-Dideoxy-2',3'-didehydrothymine (D4T); A Potent and Selective Agent Against Human Immunodeficiency Virus (HIV)". The authors are myself, applicants Lin and Prusoff and I. Ghazzouli, M. Hitchcock, V. Brankovan, J. Desiderio, M. Mansuri and J. Martin.

4. The enclosed Abstract reports the results of our work in applying the subject invention, namely, a method of treating hosts infected with a retrovirus, e.g., HIV, using 3'-deoxythymidine-2'-ene (3'-deoxy-2',3'-didehydrothymidin).

5. The enclosed Abstract reports that the anti-HIV potency of 2',3'-dideoxy-2',3'-didehydrothymidine (=3'-deoxythymidine-2'-ene=3'-deoxy-2',3'-didehydrothymidin) ("D4T") was found to be significantly less toxic than AZT (azidothymidine), i.e., the concentration required for 50% inhibition of granulocyte monocyte colony-forming units was 100 times less for D4T as compared to AZT.

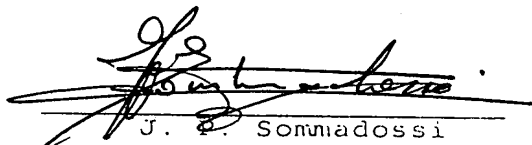
6. To date, out of all the anti-retroviral tested under my supervision, the compound recited in applicants' claims was one of the most impressive compound evaluated in that it was 100-fold less toxic than the presently used AZT.

7. In my expert opinion, applicants have achieved an extraordinary, unexpected and unusual advance in the art of retroviral treatment.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Date

4/5/88


J. P. Sommadossi